II. Remarks

A. Status of the claims

Claims 18, 22, 26, 32-36 are pending. Claims 7, 12, 21, 23-25, 27-31 have been cancelled by this amendment without prejudice to the further prosecution of said claims in a continuation application. These claims have been cancelled solely for the purpose of expediting allowance of the present application.

Claims 18 and 22 have been amended without prejudice. New claims 32-35 and 36 have been added. Support for the amendments to the claims and support for the new claims can be found throughout the original specification as filed and in the previous claims. It is respectfully submitted that no new matter has been added by virtue of the present amendment.

B. Allowable Subject Matter

In the Office Action, the Examiner indicated that "[c]laim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims."

In view of the aforementioned and for the purposes of advancing prosecution, claim 25 has been incorporated into claim 18 (the independent claim from which it depended), without prejudice. With respect to claim 18, the Examiner's attention is further directed to the Applicants remarks with respect to the 35 U.S.C. §112, first paragraph rejection below.

Further, claims 32-36 have been added by virtue of this amendment. Claims 33-36 are directed to suppository delivery systems which correspond to method claims 18, 22, 26, and 32.

It is respectfully submitted that pending claims 18, 22, 26, 32-36 are enabled under 35 U.S.C. 112, first paragraph for reasons as discussed below with respect to the 35 U.S.C. §112, first paragraph rejection of claims 7, 12, 21-24, and 27-31.

C. 35 U.S.C. §112, first paragraph

In the Office Action, claims 7, 12, 21-24, and 27-31 were rejected under 35 U.S.C. 112, first paragraph, based on the Examiner's position that "the specification while being enabling for compositions that comprise a suppository base that comprises both polyethylene glycol and polysorbate together with a microbial pathogen or adjuvants for induction of an immune response, and specifie vaccine compositions that comprise whole bacterial pathogens of known vaccine antigent, and viruses excluding HIV virus for induction of a prophylactic immune response, does not reasonably provide enablement for the administration of any vaccine adjuvant, or any suppository composition based delivery system that comprises any whole microbial pathogens, or any antigen, or nucleic acid that encodes an antigen derived therefrom for induction of a protective prophylactic immune response and used for the stimulation of a protective immune response that prevents (prophylactic) infection." (citations omitted).

This rejection is traversed. As noted by the Examiner, the specification is enabling for compositions that comprise a suppository base that comprises both polyethylene glycol and polysorbate together with a microbial pathogen or adjuvants for induction of an immune response. Further, in the previous office action of June 25, 2004, the Examiner already acknowledged enablement of the pending claims at that time by withdrawing the 35 U.S.C. 112, first paragraph rejection, stating that the "35 U.S.C. 112, first paragragh (scope of enablement), has been obviated through amendment of the

claims to be directed to compositions for the induction of an immune response." See, e.g., Office Action of June 25, 2004 at page 3.

The Examiner is respectfully reminded that "[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988); MPEP 2164.01 (8th Edition, Rev. 2). "Nothing more than objective enablement is required, and therefore, it is irrelevant whether [a] teaching is provided broad terminology or illustrative examples." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); MPEP 2164.01 (8th Edition, Rev. 2).

It is respectfully submitted that once having arrived at the inventive concept, the formulation of a suppository delivery system for the inclusion of a vaccine or vaccine adjuvant comprising microbial pathogens as in the present invention, one skilled in the art having the information contained in the present specification would without undue experimentation be able to manufacture formulations falling within the claims such as those discussed in the present specification. The present specification teaches that the claimed vaccines and vaccine adjuvant(s) may be formulated in a variety of ways. (See, e.g., page 11, lines 1-4; page 13, line 14 to page 14, line 2; and throughout the specification). Additionally, simply by way of example and without limitation, U.S. Patent 6,088,853, from which the present application claims priority, provides evidence that microbial pathogens included in a suppository delivery system and inserted into the urogenital orifice of humans is capable of preventing pathogenic infections in humans. Further, the example of U.S. Patent No. 6,088,853 indicates that in vivo protective immunity was achieved in the subjects with the vaccine exemplified.

The case law does not require each possible formulation encompassed by the claims to be exemplified. See e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 84 (CCPA 1970); MPEP 2164.01(b) (8th Edition, Rev. 2) ("As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied.").

Therefore, the Applicants are not required to exemplify every formulation which would be encompassed by the claim. If the application provides sufficient guidance for one of ordinary skill in the art to manufacture formulations proposed by the disclosure of the present application then the claim is enabled.

In the present application, Applicants are claiming in amended claim 18, a method for producing an immune response in humans or animals, said method comprising the steps of (a) inserting a suppository into a urogental orifice of a human, wherein said suppository comprises a vaccine or vaccine adjuvant(s) of microbial pathogens capable of producing humoral or cellular-mediate immunity . . . ."; and in new claim 33, a suppository based delivery system for induction of an immune response in humans, said suppository comprising a vaccine or vaccine adjuvant(s) of microbial pathogens, capable of producing humoral or cellular-mediated immunity against urogenital disease in humans . . . .

Applicants have provided a representative example of the claimed formulation in the present application, and the priority patent provides evidence that a vaccine of microbial pathogens administered in a vaginal suppository, as claimed in the present invention, can be manufactured by one of ordinary skill in the art without undue experimentation. In view of the aforementioned, it is respectfully submitted that sufficient guidance is provided for one of ordinary skill in the art to manufacture the suppositories presently claimed and previously claimed.

Therefore, the Examiner is respectfully requested to acknowledge the enablement of the present pending claims 18, 22, 26, 32-36 under 35 U.S.C. §112, first paragraph.

D. 35 U.S.C. § 102 Rejections

1. U.S. Patent No. 4,873,090 (Clancy)

In the Office Action, the Examiner rejected claims 7, 18, 23, and 27 under 35 U.S.C. 102(b) as being anticipated by Clancy (U.S. 4,873,090).

As claims 7, 23, and 27 have been cancelled without prejudice and claim 18 has been amended without prejudice to incorporate claim 25 as suggested by the Examiner, this rejection is now moot.

2. U.S. Patent No. 5,712,257 (Carter)

In the Office Action, the Examiner rejected claims 7, 18, 23, 26-27, and 29 under 35 U.S.C. 102(b) as being anticipated by Carter (U.S. 5,712,257).

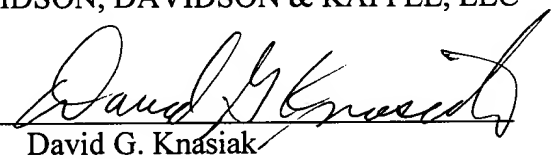
As claims 7, 23, 26-27, and 29 have been cancelled without prejudice and claim 18 has been amended without prejudice to incorporate claim 25 as suggested by the Examiner, this rejection is now moot.

III. CONCLUSION

It is now believed that the above-referenced rejections have been obviated. It respectfully submitted that all claims are now in condition for allowance.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if she believes that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
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